



Patent

Attorney's Docket No. 1016800-000626

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of

Melanie Chopart et al.

Application No.: 10/766,016

Filed: January 29, 2004

For: RECONSTRUCTED
EPIDERMIS/SKIN EQUIVALENT
COMPRISING A CERAMIDE 7 AND
/OR 5.5 AND LIPID LAMELLAR
VESICULAR COMPOSITIONS
COMPRISING CERAMIDE 7
AND/OR 5.5 COMPOUNDS

) Group Art Unit: 1651

) Examiner: HERBERT J. LILLING

) Confirmation No.: 2670

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) VA 22313-1450 on August 18, 2006.

) By: _____

) Kim A. Cabello

RESPONSE TO RESTRICTION REQUIREMENT/ELECTION OF SPECIES

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In response to the Restriction Requirement dated June 23, 2006, Applicants submit the following response. A petition for a one-month extension of time extending the period for response from July 23, 2006 to August 23, 2006 is attached hereto.

In the Official Communication mailed on June 23, 2006, the Examiner sets forth a restriction requirement among five groups of the claims:

Group I, claims 1-16 and 44, drawn to a method for preparing a reconstructed epidermis/skin equivalent from a culture medium;

Group II, claims 17 and 43, drawn to a method of applying a composition which comprises lipid lamellar vesicles onto the face surface;

Group III, claims 18-39, drawn to a composition comprising a dispersion, in an external aqueous phase, of vesicles which comprise lipid lamellar phases separated from each other by hydrophilic layers, said lamellar phases comprising at least one amphiphilic lipid and at least one ceramide 7 and/or 5.5;

Group IV, claims 40-42, drawn to a method for treating epidermis, atopic skin or skin of humans by applying a composition; and

Group V, claims 45-47, drawn to epidermis/skin equivalent comprising formula I.

1. ELECTION OF GROUP III

Applicants herewith elect Group III, claims 18-39, drawn to a composition comprising a dispersion, in an external aqueous phase, of vesicles which comprise lipid lamellar phases separated from each other by hydrophilic layers, said lamellar phases comprising at least one amphiphilic lipid and at least one ceramide 7 and/or 5.5, ***with traverse***.

The Applicants traverse the Restriction Requirement for at least the following reasons. Under M.P.E.P § 803, a restriction is proper if the subject matter can be restricted into one of two or more claimed inventions, and these inventions are either independent (M.P.E.P § 806.04) or distinct (M.P.E.P § 806.05). However, the

second element, "distinct", is not satisfied for a proper restriction requirement if the search and examination of an entire application can be made without serious burden. In such instances the Examiner must examine the entire application on the merits, even though it includes claims to independent and distinct inventions.

Applicants respectfully submit that the inventions of Groups I to V are closely related and that a proper search of any of the claims should, by necessity, require a proper search of the others. Applicants respectfully request reconsideration of the restriction and rejoinder of the claims at least with respect to the elected Group III, drawn to a composition which comprises lipid lamellar phases; Group II, drawn to lipid lamellar vesicles; and Group IV, drawn to methods for treating epidermis by applying said composition. Thus, a search of the claims of Group III necessarily substantially overlaps that of Groups II and IV.

Applicants submit that any nominal burden placed upon the Examiner to search accordingly to determine the art relevant to Applicants' overall invention is significantly outweighed by the public's interest in not having to obtain and study many separate patents in order to have available all of the issued patent claims covering Applicants' invention. The alternative is to proceed with the filing of multiple applications, each consisting of generally the same disclosure, and each being subjected to essentially the same search, perhaps by different Examiners on different occasions. This process would place an unnecessary burden on both the Patent and Trademark Office and on the Applicants.

2. SPECIES ELECTION

The Examiner further sets forth four groups of species:

- a species for lipids of claims 24-30;
- a species for an additional compound for improving the barrier function of claim 37;
- a species of a bioactive agent in claim 38; and
- a species of claim 39, electing an additional adjunct.

To be fully responsive with the Restriction Requirement, Applicants provisionally elect, **with traverse**, the species comprising the amphiphilic lipid, palmitate sorbitan (claims 24-30); the species comprising the ionic amphiphilic lipid, lipamino acid (claims 24-30); cholesterol, as the additional compound for improving barrier function (claim 37); desquamating agents (claim 38); and the species of antioxidants as the adjuvant (claim 39). It is believed that claims 18, 24-26, 27-31, 37, 38 and 39 are readable upon the elected species, respectively.

With regard to the required species elections, Applicants once again draw the Examiner's attention to M.P.E.P. § 803, which recites: "If the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to independent and distinct inventions." No basis as to why a search of these categories would be burdensome, let alone seriously burdensome, has been set forth in the Official Communication, as required.

In addition to showing the serious burden, the Patent Office is also under an obligation to demonstrate that the species are independent and/or distinct. M.P.E.P. § 806.04(b). No basis has been provided in the Official Communication as to why

the various members of the generic classes in question are independent and/or distinct. Without meeting this obligation, the requirements have not been properly evinced. Furthermore, no evidence was provided why the instant elections are necessary in view of the claims and art.

The Applicants further submit that, under 37 C.F.R. § 1.141 and M.P.E.P. § 806.04(a), a reasonable number of species may still be claimed in one application. The Patent Office has not provided any explanation as to why the species could not be examined together. See M.P.E.P. § 808.01(a).

Applicants submit that the search and examination burden on the Examiner to examine all the claims directed to a product comprising or a method using lipid lamellar phases is not undue. At the very least, Applicants request rejoinder of Group III with Groups II and IV.

Accordingly, as no distinction was presented and no explanation of why the amount of species was seriously burdensome on the Examiner, the Applicants respectfully request reconsideration of the additional restriction and species elections, and requests their withdrawal.

Applicants have no intention of abandoning any non-elected subject matter and should it be necessary, Applicants expressly reserve the right to file one or more continuation and/or divisional applications directed to non-elected subject matter.

CONCLUSION

Accordingly, for at least all of the above reasons, withdrawal of the requirement for restriction is requested and believed to be in order. Further and favorable consideration of all claims on record on the merits is respectfully requested.


In the event of any questions, regarding this Response or the application in general, it would be very much appreciated if the Examiner would telephone the undersigned agent concerning such questions, so that the prosecution of the instant application may be expedited.

Respectfully submitted,

BUCHANAN INGERSOLL & ROONEY LLC

Date: August 18, 2006

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